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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,579	12/09/1999	MILES B. BRENNAN	3718-6	9014

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GENERAL NUMBER 00757
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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/458,579	Applicant(s) BRENNAN ET AL.	
	Examiner Jegatheesan Seharaseyon	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11/21/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 15, 16, 19, 20, 22-29 and 35-37 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 19-20, 22-29 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the remarks and declaration filed on 11/21/04.

Claims 1-5, 15, 16, 19, 20, 22-29 and 35-37 are pending. Claims 1-5, 15 and 16 were allowed previously.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. The declaration of Dr. Victor J. Hurby under 37 CFR 1.132 filed 11 November 2003 is insufficient to overcome the rejection of claims 19-20, 22-29 and 35-37 based upon the rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and lacking in the scope of enablement as set forth in the last Office action because: (1) The declaration provided by Dr. Hurby is an opinion with no evidence to support his position or Applicants' position with respect to peripheral melanocortin receptors. Specifically, Dr. Hurby states that at the time of filing this application (12/9/1999), those practicing in this field believed that MC1-R, MC2-R, MC3-R, MC4-R and MC5-R were found in the periphery but offers no evidence to substantiate that claim.

(2) Contrary to the declaration, it was accepted in the art at the time of filing that MC4-R was a central nervous system receptor (Lee et al. U. S. Patent No; 5,908,609, column 2, lines 5-25).

4. Please provide Office with a list of all pending claims.

Claim Rejections - 35 USC § 112, first paragraph maintained

5. Claims 19-20, 22-29 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejections of claims 19-20, 22-29 and 35-37 under USC 112, first paragraph, for lacking written description is maintained for reasons set forth in Paper No: 21 (9/25/02) and Paper No: 27 (5/19/03). Applicant's remarks and declaration filed on 11/21/04 have been fully considered but are not persuasive. Specifically, the declaration provided by Dr. Hurby is an opinion with no evidence to support his position or Applicants' position with respect to peripheral melanocortin receptors. Dr. Hurby states that at the time of filing this application (12/9/1999), those practicing in this field believed that MC1-R, MC2-R, MC3-R, MC4-R and MC5-R were found in the periphery but offers no evidence to substantiate that claim. Contrary to the declaration, it was accepted in the art at the time of filing that MC4-R was a central nervous system receptor (Lee et al. U. S. Patent No; 5,908,609, column 2, lines 5-25). There is no evidence to indicate that MC1-R, MC2-R, MC3-R and MC5-R were expressed in the peripheral tissue and involved in the peripheral pathways. In fact, the specification on page: 25, line 7 states that "Peripheral adipocytes are known to express two different melanocortin receptors, melanocortin 2-receptor (MC2-R) and melanocortin 5-receptor (MC5-R)". It further states that, "the present inventors believe that these two peripheral pathway

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melanocortin receptors, the MC2-R is the most important in controlling the peripheral pathway of energy homeostasis, although both receptors may play roles in this process". Thus, clearly limiting the invention to MC2-R and MC5-R.

In pages 2-3 of the remarks Applicant asserts that it was they who for the first time disclosed the importance of a melanocortinic pathway in the peripheral regulation of energy balance. The Office does not dispute this fact. Applicant further asserts that throughout the specification, they have compared the peripheral action with central regulation. This fact is also not in dispute. In addition, Applicant states that it is the presence of the receptor at the periphery that is critical. This is also not disputed. However, what is in dispute is the fact that Applicant did not have any disclosure that any other peripheral melanocortin receptors other than MC2-R and MC5-R with a role in regulating body weight and energy homeostasis. While it true that Applicant has contrasted the peripheral action with that of the central regulation, it is noted that the Applicant has compared the binding of a compound to a peripheral melanocortin receptor (MC2-R or MC5-R) to the binding of the same compound to MC4-R the central melanocortin receptor (see page 70 lines: 13-15). Therefore, the Applicant at the time of filing did not contemplate or appreciate that MC1-R ad MC3-R receptors were involved in the regulation of body weight and energy homeostasis. Thus, the rejections of claims 19-20, 22-29 and 35-37 under USC 112, first paragraph, for lacking written description is maintained.

6. Claims 19-20, 22-29 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for MC2-R and MC4-R, does not

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reasonably provide enablement for MC1-R and MC3-R. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejections of claims 19-20, 22-29 and 35-37 under USC 112, first paragraph, for failing to satisfy the scope of enablement requirement is maintained for reasons set forth in Paper No: 21 (9/25/02), Paper No: 27 (5/19/03) and above in paragraph 4.

Applicant's remarks and declaration filed on 11/21/04 have been fully considered but are not persuasive. Specifically, the declaration provided by Dr. Hurby is an opinion with no evidence to support his position or Applicants' position with respect to peripheral melanocortin receptors. Dr. Hurby states that at the time of filing this application (12/9/1999), those practicing in this field believed that MC1-R, MC2-R, MC3-R, MC4-R and MC5-R were found in the periphery but offers no evidence to substantiate that claim. Contrary to the declaration provided by Dr. Hurby, it was accepted in the art at the time of filing that MC4-R was a central nervous system receptor (Lee et al. U. S. Patent No; 5,908,609, column 2, lines 5-25).

Although, the specification discloses melanocortin receptors MC1-R through MC5-R, it appears that the Applicant recognized only MC2-R and /or MC5-R to be the peripheral receptors with the ability to stimulate lipolysis and/or to inhibit fatty acid uptake by adipocytes, and in particular, to control obesity (see pages: 65-68; page: 76, lines 23-25). There is no correlation or suggestion of other melanocortin receptors namely MC1-R and MC3-R being involved in the regulation of body weight and energy homeostasis. Despite the knowledge in the art of the other melanocortin receptors, the

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specification fails to provide any guidance to the use of MC1-R and MC3-R in the regulation of body weight and energy homeostasis. In fact, the specification on page: 25, line 7 states that "Peripheral adipocytes are known to express two different melanocortin receptors, melanocortin 2-receptor (MC2-R) and melanocortin 5-receptor (MC5-R)". It further states that, "the present inventors believe that these two peripheral pathway melanocortin receptors, the MC2-R is the most important in controlling the peripheral pathway of energy homeostasis, although both receptors may play roles in this process". Thus, clearly limiting the invention to MC2-R and MC5-R.

Therefore the amount of experimentation required to make and/or use the full scope of claimed receptors would require undue trial and error experimentation. Given the breadth of claims 19-20, 22-29 and 35-37 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior art of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the full scope of the claimed invention.

7. Claims 1-5, 15 and 16 are allowed. Claims 19-20, 22-29 and 35-37 are rejected.

However, claims that are drawn to methods of using MC2-R and MC5-R receptors for the detection of compounds involved in the regulation of bodyweight and energy homeostasis remain allowable over prior art.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

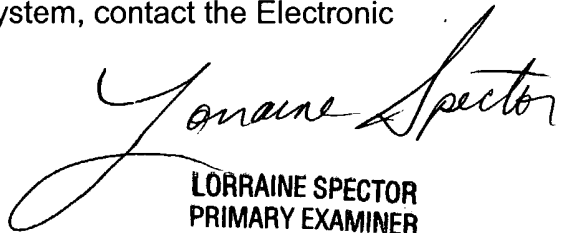
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LORRAINE SPECTOR
PRIMARY EXAMINER